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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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BAXTER HEALTHCARE CORPORATION
1 BAXTER PARKWAY
DF2-2E
DEERFIELD, IL 60015

EXAMINER

MORGAN, ROBERT W

ART UNIT PAPER NUMBER

3626

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/720,765

Applicant(s)

MARTUCCI ET AL.

Examiner

Robert W. Morgan

Art Unit

3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure filed 7/14/04 and 2/24/04 have been acknowledge and entered in the application.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Pub. 2001/0044731 to Coffman et al. in view of U.S. Patent No. 6,988,075 to Hacker.

As per claim 1, Coffman et al. teaches a method for medication delivery comprising the steps of:

(a) providing a medication container containing a prescribed medication and a first label containing data on the prescribed medication and instruction of delivering of the medication, the prescribed medication data and the instruction of delivering the medication being provided in machine readable format is met by the medication container including a copy of the order, or at a minimum the patient's name, the drug name, and the appropriate treatment parameters are represented on the label affixed to container and the information may be represented by a bar code (see: paragraph 53);

(c) providing a handheld computing device MTC (110, Fig. 1) with:

means for reading the prescribed medication data and medication delivery instruction from the first label is met by the medical transaction carrier MTC (110, Fig. 1) which could be a personal digital assistant or lap top (see: paragraph 16) interfacing with nurse computer (60, Fig. 1) by a cradle (100, Fig. 1) (see: paragraph 33). In addition, Coffman et al. teaches that the nurse computer (60, Fig. 1) includes a bar code reader (80, Fig. 1) for reading bar codes on medication labels, reports or other items having bar coded labels provided for identification (see: paragraph 32). The Examiner considers the MTC and nurse computer to be one entity or computer and therefore a handheld computing device;

means for storing the data and instruction is met by the MTC (110, Fig. 1) including magnetic strip card, a PCMCIA card, RF-ID, or other non-volatile memory storage media (see: paragraph 39);

means for communicating data and instruction to other electronic devices is met by the MTC (110, Fig. 1) may have a storage capability and technology for interfacing with a computer system network so that information may be communicated between the MTC (110, Fig. 1) and other device, such as computer, clinical devices and the like (see: paragraph 34);

(d) the handheld computing device reading the prescribed medication data and medication delivery instruction from the first label is met by the technology that allows for reading a bar code applied to medication, or could employ optical recognition, some form of active detection using a transmitter/receiver or smart chip or computer either embedded in the label of the medication or located on the medication container or other method of positively identifying the medication (see: paragraph 107); and

(f) the handheld computing device performing a matching check and confirming the match between the prescribed medication data and the patient data is met by the system validating each medication delivered to a patient to make sure it is identical to the medication that is indicated in the information contained within the MTC (see: paragraph 107).

Coffman et al. fails to teach:

(b) providing a tag adapted to be worn by a patient, the tag having a second label containing data of the patient, the patient data being provided in machine readable format;

(e) the handheld computing device reading the patient data from the second label.

Hacker teaches an electronic medical record system that includes a unique access identification means for a patient such as bracelet with a unique bar code for each patient (see: column 7, lines 43-50 and column 11, lines 45-49).

One of ordinary skill in the art at the time the invention was made would have found it obvious to include the bar coded bracelet worn by the patient containing identification information as taught by Hacker within the distributed remote asset and medication management drug delivery system as taught by Coffman et al. with the motivation using a patient identifier in order to access the electronic medical record (see: Hacker: column 6, lines 25-29).

As per claim 2, Coffman et al. teaches the claimed step of the handheld computing device communicating and downloading the medication delivery instruction to a medication delivery device to deliver the medication to the patient. This limitation is met by the information downloaded to the MTC (110, Fig. 1) from the control system (40, Fig. 1), the MTC (110, Fig. 1) is ready to accompany the medication to the patient area for treatment of the patient (see: paragraph 61).

As per claim 3, Coffman et al. teaches the claimed step of the medication delivery device performing periodic checks of the operating parameters of the medication delivery device against the medication delivery instruction downloaded from the handheld computing device to ensure the operating parameters are within the ranges set by the medication delivery instruction after starting the delivery of the medication. This feature is met by the infusion pump that may be programmed to check over predetermined period of time, such as an hour, for infusion instruction or parameters and if not received the infusion is stopped (see: paragraph 97).

As per claim 4, Coffman et al. teaches the claimed the first label is encoded with the prescribed medication data and the instruction of delivering the medication derived from a print stream generated from a pharmacy information system. This limitation is met by the pharmacy that package the medication container including a copy of the order, or at a minimum the patient's name, the drug name, and the appropriate treatment parameters are represented on the label affixed to container (see: paragraph 53). The information may be represented by a bar code, or it may be stored in smart label, such as a label having an embedded computer or passive device (see: paragraph 53).

As per claim 5, Coffman et al. teaches a method for medication delivery comprising the steps of:

(a) providing a medication container containing a prescribed medication and a first label containing data on the prescribed medication and instruction of delivering of the medication, the prescribed medication data and the instruction of delivering the medication being provided in machine readable format is met by the medication container including a copy of the order, or at a minimum the patient's name, the drug name, and the appropriate treatment parameters are

Art Unit: 3626

represented on the label affixed to container and the information may be represented by a bar code (see: paragraph 53);

(c) providing a handheld computing device MTC (110, Fig. 1) with:

means for reading the prescribed medication data and medication delivery instruction from the first label is met by the medical transaction carrier MTC (110, Fig. 1) which could be a personal digital assistant or lap top (see: paragraph 16) interfacing with nurse computer (60, Fig. 1) by a cradle (100, Fig. 1) (see: paragraph 33). In addition, Coffman et al. teaches that the nurse computer (60, Fig. 1) includes a bar code reader (80, Fig. 1) for reading bar codes on medication labels, reports or other items having bar coded labels provided for identification (see: paragraph 32). The Examiner considers the MTC and nurse computer to be one entity or computer and therefore a handheld computing device;

means for storing the data and instruction is met by the MTC (110, Fig. 1) including magnetic strip card, a PCMCIA card, RF-ID, or other non-volatile memory storage media (see: paragraph 39); and

means for communicating data and instruction to other electronic devices is met by the MTC (110, Fig. 1) may have a storage capability and technology for interfacing with a computer system network so that information may be communicated between the MTC (110, Fig. 1) and other device, such as computer, clinical devices and the like (see: paragraph 34); and

(d) the handheld computing device reading the prescribed medication data and medication delivery instruction from the first label is met by the technology that allows for reading a bar code applied to the medication, or could employ optical recognition, some form of active detection using a transmitter/receiver or smart chip or computer either embedded in the

Art Unit: 3626

label of the medication or located on the medication container or other method of positively identifying the medication (see: paragraph 107);

(f) the handheld computing device performing a matching check and confirming the match between the prescribed medication data and the patient data is met by the system validating each medication delivered to a patient to make sure it is identical to the medication that is indicated in the information contained within the MTC (see: paragraph 107); and

(g) the handheld computing device communicating and downloading the medication delivery instruction to a medication delivery device to deliver the medication to the patient is met by the information downloaded to the MTC (110, Fig. 1) from the control system (40, Fig. 1), the MTC (110, Fig. 1) is ready to accompany the medication to the patient area for treatment of the patient (see: paragraph 61).

Coffman et al. fails to teach:

(b) providing a tag adapted to be worn by a patient, the tag having a second label containing data of the patient, the patient data being provided in machine readable format; and

(e) the handheld computing device reading the patient data from the second label.

Hacker teaches an electronic medical record system that includes a unique access identification means for a patient such as bracelet with a unique bar code for each patient (see: column 7, lines 43-50 and column 11, lines 45-49).

The obviousness of combining the teachings of Hacker within the teachings of Coffman et al. are discussed in rejection of claim 1, and incorporated herein.

As per claim 6, Coffman et al. teaches a method for medication delivery comprising the steps of:

(a) identifying medication data contained in a first label on a medication container containing a prescribed medication, the first label containing data on the prescribed medication and instruction of delivering of the medication, the prescribed medication data and the instruction of delivering the medication being provided in machine readable format is met by the medical transaction carrier MTC (110, Fig. 1) which could be a personal digital assistant or lap top (see: paragraph 16) interfacing with nurse computer (60, Fig. 1) by a cradle (100, Fig. 1) (see: paragraph 33). In addition, Coffman et al. teaches that the nurse computer (60, Fig. 1) includes a bar code reader (80, Fig. 1) for reading bar codes on medication labels, reports or other items having bar coded labels provided for identification (see: paragraph 32). The Examiner considers the MTC and nurse computer to be one entity or computer and therefore a handheld computing device;

(c) performing a matching check between the medication data and the patient data by a handheld computing device wherein the handheld computing device is met by the system validating each medication delivered to a patient to make sure it is identical to the medication that is indicated in the information contained within the MTC (see: paragraph 107), having:

means for reading the prescribed medication data and medication delivery instruction from the first label is met by the medical transaction carrier MTC (110, Fig. 1) which could be a personal digital assistant or lap top (see: paragraph 16) interfacing with nurse computer (60, Fig. 1) by a cradle (100, Fig. 1) (see: paragraph 33). In addition, Coffman et al. teaches that the nurse computer (60, Fig. 1) includes a bar code reader (80, Fig. 1) for reading bar codes on medication labels, reports or other items having bar coded labels provided for identification (see: paragraph

Art Unit: 3626

32). The Examiner considers the MTC and nurse computer to be one entity or computer and therefore a handheld computing device;

means for storing the data and instruction is met by the MTC (110, Fig. 1) including magnetic strip card, a PCMCIA card, RF-ID, or other non-volatile memory storage media (see: paragraph 39); and

means for communicating data and instruction to other electronic devices is met by the MTC (110, Fig. 1) may have a storage capability and technology for interfacing with a computer system network so that information may be communicated between the MTC (110, Fig. 1) and other device, such as computer, clinical devices and the like (see: paragraph 34);

(d) the handheld computing device confirming the data and downloading the instruction of delivering the medication to a medication delivery device is met by the information downloaded to the MTC (110, Fig. 1) from the control system (40, Fig. 1), the MTC (110, Fig. 1) is ready to accompany the medication to the patient area for treatment of the patient (see: paragraph 61).

Coffman et al. fails to teach:

(b) identifying patient data contained in a second label on a tag adapted to be worn by a patient, the second label containing data of the patient, the patient data being provided in machine readable format.

Hacker teaches an electronic medical record system that includes a unique access identification means for a patient such as bracelet with a unique bar code for each patient (see: column 7, lines 43-50 and column 11, lines 45-49).

The obviousness of combining the teachings of Hacker within the teachings of Coffman et al. are discussed in rejection of claim 1, and incorporated herein.

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

In related art (5,822,544) Chaco et al. discloses a patient care and communication system that utilizes a central processing and a plurality of remote stations electrically connected to the central processing system.

In related art (5,867,688) Simmons et al. shows a data retrieval and acquisition system having a wireless handheld interface for data entry by the user.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert W. Morgan whose telephone number is (571) 272-6773. The examiner can normally be reached on 8:30 a.m. - 5:00 p.m. Mon - Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3626

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert Morgan
Robert Morgan
Patent Examiner
Art Unit 3626